UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF TENNESSEE AT CHATTANOOGA

UNITED STATES OF AMERICA

v. **CASE NO. 1:18-cr-11**
Judge Mattice/Steger

JERRY WAYNE WILKERSON,
MICHAEL CHATFIELD,
KASEY NICHOLSON,
BILLY HINDMON, and
JAYSON MONTGOMERY

JOINT MOTION TO DISMISS AND INCORPORATED MEMORANDUM OF LAW

Defendants Jerry Wayne Wilkerson, Kasey Nicholson, Billy Hindmon, and Jayson Montgomery, by and through undersigned counsel, hereby submit this Joint Motion to Dismiss, pursuant to Rule 12(b), Fed.R.Crim.P., and E.D. Tenn. LR 5.1 and LR 7.1. Defendant Michael Chatfield, by and through undersigned counsel, joins and adopts the arguments of facts and law contained in paragraphs 1-33, 47-74, and 84-91 that relate specifically to Mr. Chatfield. As grounds therefore, the Defendants state the following:

I. INTRODUCTION

1. The government filed an Indictment against Mr. Chatfield on January 23, 2018. Then, the government filed a Superseding Indictment against the defendants on or about September 25, 2018, filed a Second Superseding Indictment on March 26, 2019, and filed a Third Superseding Indictment (the "Indictment") on May 29, 2019. This Motion is filed in response to the Third Superseding Indictment.
2. The Indictment alleges violations of 42 USC § 1320a-7b(b)(1) and (2) (Receipt and Payment of Illegal Remuneration);18 USC § 1347 (Health Care Fraud);18 USC §

1349 (Conspiracy to Commit Health Care Fraud);18 USC § 1341 (Mail Fraud); 18 USC § 1343 (Wire Fraud); and, 18 USC § 1957 (Money Laundering).

3. The Indictment alleges that Mr. Wayne Wilkerson, by and through his company, Top Tier Medical, LLC ("Top Tier"), engaged in a scheme to defraud commercial and government health insurance plans by marketing compounded pharmaceuticals in violation of applicable laws.

4. As a threshold matter, the Indictment alleges:

   a) the defendants marketed compounded pharmaceuticals to physicians and patients on behalf of pharmacies;

   b) the patients' physicians wrote prescriptions for the patients;

   c) the medications were on the patients' insurance plans' formularies, at the plans' pre-set rates of reimbursement;

   d) the pharmacies compounded and dispensed the medications to the patients based on the physicians' prescriptions;

   e) the patients received the medications;

   f) the pharmacies billed the patients' insurance plans and were paid the pre-set rates of reimbursement for the medications;

   g) multiple patients in turn became marketers in the same manner as the defendants; and,

   h) the defendants were paid by the pharmacies a portion of the insurance reimbursement as a sales commission for their marketing.

5. The Indictment alleges that such arrangements constitute a criminal scheme because:

a) the physicians' prescribing was for patients with no pre-existing medical condition or medical necessity for the medications;

b) the patients did not consent to receive the medications;

c) the defendants misled some patients as to their insurance plans' copayments for the medications;

d) the defendants reimbursed some patients for their medication copayments;

e) the defendants failed to disclose to the patients the cost of the prescriptions to be paid by the patients' insurance plans to the pharmacies;

f) the defendants provided financial inducements to some patients in exchange for the patients themselves becoming sales representatives;

g) the defendants employed medical professionals who prescribed compounded pharmaceuticals to some patients;

h) those employed medical professionals failed to properly examine and treat some patients prior to prescribing;

i) the pharmacies paid sales commissions to the defendants; and,

j) the defendants targeted specific insurance plans and specific medications based upon those plans' medication coverage and reimbursement.

6. An indictment may be dismissed pursuant to Rule 12(b), Fed.R.Crim.P. where a defendant can show that the indictment fails to state a cause of action for the commission of a federal crime. *U.S. v. Abboud*, 438 F.3d 554, 566 (6th Cir. 2006).

7. Here, the Indictment is subject to dismissal because: a) none of the alleged acts or failures to act by the defendants constitute a violation of any of the statutes cited in the Indictment; b) even if all the allegations are taken as true, they are legally

immaterial; and c) there is no showing that the defendants were in legal control of the circumstances.

8. First, the Indictment (primarily at ¶¶ 1 – 4 and 8 – 17 of the Indictment), fails to allege that the defendants violated any federal laws, as follows:

   a) whether or not the medications were prescribed pursuant to pre-existing conditions or medical necessity is the sole responsibility and authority of the patients' physicians and not the defendants because non-physicians such as the defendants cannot as a matter of law write prescriptions, as erroneously alleged in paragraph 8. *U.S. v. Vernon*, 723 F.3d 1234, 1254-55 (11th Cir. 2013); *U.S. v. Miles*, 360 F.3d 472, 480-81 (5th Cir. 2004); *U.S. v. Polin*, 194 F.3d 863, 864-65, 867 (7th Cir. 1999); *U.S. v. Starks*, 157 F.3d 833, 835-36 (11th Cir. 1998);

   b) whether or not the patients consented to receive the medications is solely the responsibility and authority of the prescribing physicians and dispensing pharmacies, and not the defendants, as erroneously alleged in paragraph 11. *Moore v. Wyeth-Ayerst Laboratories*, 236 F.Supp.2d 509, 512-13 (D. Md. 2002) (Describing in general the respective responsibilities of physicians and pharmacies as to pharmaceutical dispensing);

   c) whether or not the patients received accurate and complete information as to copayments is solely the responsibility and authority of the dispensing pharmacies and not the defendants, as erroneously alleged in paragraphs 2 and 11. *Sausalito Pharmacy, Inc. v. Blue Shield of California*, 544 F.Supp. 230, 232 (N.D. Cal. 1981) ("[T]he deductible or copayment, is collected by the pharmacy from the insured."); *U.S. ex rel. Grenadyor v. Ukranian Village Pharmacy, Inc.*,

895 F.Supp.2d 872, 875 (N.D. Ill. 2012) (Medicare false claims case alleging fraud due to the "systematic failure of UV Pharmacy to charge customers a copayment . . . .");

d) whether or not the defendants reimbursed any patients for their copayments, such alleged acts do not violate federal law because the legal duty to collect copayments is solely that of the pharmacies, as erroneously alleged in paragraph 11. *Sausalito Pharmacy, Inc. v. Blue Shield of California*, 544 F.Supp. at 232; *U.S. ex rel. Grenadyor v. Ukranian Village Pharmacy, Inc.*, 895 F.Supp.2d at 875;

e) whether or not the defendants withheld information from patients, such as the reimbursement expense to be borne by the patients' insurance plans, such alleged failures to inform do not violate federal law, as even the pharmacies do not have a legal duty to disclose drug pricing to patients, as erroneously alleged in paragraphs 2, 11, and 16. *Corcoran v. CVS Health Corp.*, 169 F.Supp.3d 970, 988-89 (N.D. 2016) ("Plaintiffs cite no authority for the proposition that pharmacists have superior or specialized knowledge of the nature of drug pricing such that a duty arose in this case. Pharmacists have [only] a duty of care to accurately fill a prescription. . . . As such, the Court declines Plaintiffs' invitation to impose a duty on pharmacists as a matter of law which encompasses matters of drug pricing.");

f) whether or not the defendants and others who were both patients and sales representatives received both medications and sales commissions, such alleged acts do not violate any known provision of federal law, as erroneously alleged in

paragraphs 2, 4, 8, 11 and 12;

g) whether or not the defendants employed some of the prescribing physicians, such alleged acts do not violate federal law, as erroneously alleged in paragraphs 3, 15, and 16. 42 CFR § 1001.952(i); *Joint Technology, Inc. v. Weaver*, Case No. CIV-11-846, p. 4 (W.D. Okla. 2013) ("[T]he Act [42 USC § 1320a— 7b(b)] does not prohibit 'any amount paid by an employer to an employee (who has a bona fide employment relationship with such employer) for employment in the provision of covered items or services.'"); and

h) whether or not the defendants targeted specific insurance plans based upon those plans' formularies and rates of reimbursement, such alleged acts do not violate any known provision of federal law, as erroneously alleged in paragraphs 1, 11 and 13.

10. Second, because any alleged non-compliance in the defendants' marketing could not have overcome the clinical decision-making of the physicians and pharmacies involved, such alleged acts were legally immaterial, as erroneously alleged in paragraphs 1, 2, 3, 4, 8, 9, 10, 11, 12, 13, 14, 15 and 16.

11. Third, there is no showing in the Indictment that the defendants were adequately in control of the arrangement to be guilty of a crime, because:

a) the defendants did not, and could not, have written any prescription for any patient, as mis-alleged in paragraphs 2, 4, 8, 11, and 13;

b) the defendants did not, and could not, have caused or stopped the writing of any prescription for any patient, as mis-alleged in paragraphs 3, 15, and 16;

c) the defendants did not, and could not, have compounded or dispensed any compound medication, as mis-alleged in paragraph 2;

d) the defendants did not, and could not, have possessed or used a participating provider contract with any health plan, as mis-alleged in paragraphs 2 and 11;

e) the defendants did not, and could not, have submitted any claims for payment to any health care plan, as mis-alleged in paragraphs 2, and 11;

f) the defendants did not, and could not, have established any health plan's formulary (each health plan establishes what drugs are a covered benefit for its enrollees), as mis-alleged in paragraphs 11 and 13;

g) the defendants did not, and could not, have established any health plan's pricing for its formulary (each health plan establishes what prices it pays for its own covered drugs), as mis-alleged in paragraphs 11 and 13; and

h) the defendants did not, and could not, have over-ridden any "freedom of choice" election by a prescribing physician or patient to use a pharmacy that had not contracted the defendants as a marketing agent, as mis-alleged in paragraphs 3, 15, and 16.

II. LEGAL ARGUMENT

A. Legal Standards for an Indictment

12. The minimum standard for sufficiency of an indictment are that it expressly sets forth the elements of the crimes alleged and adequately notifies the defendant of what actions he or she has taken to violate such elements. *U.S. v. Ball*, 12 F.3d 214, 214 (6th Cir.1993) (A legally sufficient indictment must "set out each element of the statutory violation in order to sufficiently inform the defendant of the offense which [he] must defend."); *U.S. v. DeAndino*, 958 F.2d 146, 147-48 (6th Cir. 1992); *Allen v. U.S.*, 867 F.2d 969, 971 (6th Cir. 1989).

13. In this case, the Third Superseding Indictment only partially sets forth the elements of the crimes alleged, and is entirely insufficient in its allegations of what acts of the defendants constitute such crimes.

B. 18 USC § 1347 (Health Care Fraud)

14. The elements of Health Care Fraud are: a) knowingly devising a scheme or artifice to defraud a health care benefit program in connection with the delivery of or payment for health care benefits, items, or services; b) executing or attempting to execute this scheme or artifice to defraud; and, c) acting with intent to defraud.

    U.S. v. Martinez, 588 F.3d 301, 314-15 (6th Cir. 2009), *cert. denied*, 131 S. Ct. 538 (2010); *U.S. v. Hunt*, 521 F.3d 636, 645 (6th Cir. 2008).

15. The statute, 18 USC § 1347, defines health care fraud as obtaining health care benefit program moneys "by means of false or fraudulent pretenses, representations or promises." *U.S. v. Davis*, 490 F.3d 541, 546 (6th Cir. 2007).

16. "False or fraudulent pretenses" requires a showing of "some deception" to induce another to give up property or a legal right. *U.S. v. Raithatha*, 368 F.3d 618, 625 (6th Cir. 2004); *U.S. v. Frost*, 125 F. 3d 346, 354 (6th Cir. 1997); *U.S. v. DeSantis*, 134 F.3d 760, 764 (6th Cir. 1998).

17. The Indictment fails to allege in any manner how the defendants misrepresented anything or misled anyone in order to deceive.

18. The Indictment alleges that the defendants failed to collect patient co-payments, or made co-payments themselves, but it is the pharmacies' responsibility to handle all aspects of compliance with patient deductibles, co-insurance, and co-payments.

19. The Indictment alleges that it is a misrepresentation/illegal omission of the defendants

that they personally utilized some medications, while concurrently being paid a commission for having marketed the same medications, yet, there is no such legal requirement to disclose this dual status to the paying health plans (and there is no allegation that the pharmacies who treated the defendants concurrently as both patient and sales representatives were in any manner misled or deceived).

20. The Indictment alleges that it is a misrepresentation/illegal omission that the defendants failed to notify patients as to the unreasonable cost to the patients' health plans of the medications at issue, yet there is no such legal requirement.

21. The Indictment alleges that the defendants' marketing of compounded medications with suspect medical necessity or where there was no pre-existing condition is a misrepresentation, but the ingredients of the medications were FDA-approved for the uses intended (or the drugs could not have been included on the health plans' formularies), and it was solely the health plans' decision to include these specific medications on their formularies (and regardless, it was solely the prescribing physicians' responsibility to properly ensure medical necessity as a clinical prerequisite to the prescribing, as a matter of state physician licensure laws). *Antares Pharma, Inc. v. Medac Pharma, Inc.*, 55 F.Supp.3d 526, 536 (D. Del. 2014) ("Insurance companies and other third party payors place drugs into formulary 'tiers,' which determine the level of co-pays and reimbursements."); *Indivior, Inc. v. Dr. Reddy's Laboratories, S.A.*, Civ. No. 17-711, p. 23 (D. N.J. 2018) ("Formularies are lists of covered drugs prepared by insurance plans and third-party payers that divide drugs into 'tiers'. These tiers dictate that how the drug is reimbursed for the patient and correlate with the type of drug covered within a tier (e.g., low cost generic drugs,

preferred brand name drugs, non- preferred brand name drugs).").

22. The Indictment alleges that the high cost of the medications demonstrates a misrepresentation/illegal omission, but it is solely the insurance plans themselves who set the prices for their own drugs. *Antares Pharma, Inc. v. Medac Pharma, Inc.*, 55 F.Supp.3d 536; *Indivior, Inc. v. Dr. Reddy's Laboratories, S.A.*, Civ. No. 17-711, p. 23.

23. Essentially, the Indictment alleges that the defendants should be held to a higher standard of pharmaceutical compliance than the licensed physicians who prescribed the medications and the licensed pharmacists that compounded, dispensed and billed the health plans for the medications (and the relevant healthcare licensure laws provide exactly the opposite – the licensed healthcare professionals are always ultimately responsible for pharmaceutical prescribing). Tenn. Code Ann. § 63-6-236.

24. The Indictment essentially alleges that the defendants should be held to a higher standard of compliance regarding relevant laws than the pharmacies who actually submitted claims for reimbursement, pursuant to the pharmacies' network provider contracts with the health plans, and there is no law to support such assertion. Tenn. Comp. R. & Regs. § 1140-03-.01(4).

25. The Indictment alleges, vaguely, that because Mr. Wilkerson employed some of the prescribing physicians in a medical spa that in some manner, such physicians were no longer ultimately responsible for the safe and efficacious prescribing of pharmaceuticals for their patients, but that is the exact opposite of the plain language of the relevant states' physician licensure requirements (in all the states where the

patients reside, no employer may affect the licensed physician's clinical judgment in any manner). Tenn. Code Ann. § 63-6-236; § 458.331(1)(q), Fla.Stat.; Code of VA, § 54.1-3303B.

26. The Indictment essentially alleges that the defendants should be held to a higher standard of claims administration than the health plans themselves, despite no law to so indicate (i.e., because the health plans failed to manage their formularies and pricing, it must somehow have been the defendants' legal responsibility to do so).

27. Because the Indictment does not, and cannot, plead that the defendants utilized "some deception" to defraud the health plans, the Indictment does not and cannot plead a cause of action under 42 USC § 1347 and therefore Counts 135 and 136 of the Indictment must be dismissed under Rule 12(b)(1), Fed.R.Crim.P.

C. 18 USC § 1349 (Health Care Fraud Conspiracy)

28. The elements of Health Care Fraud Conspiracy are: a) knowingly devising a scheme or artifice to defraud a health care benefit program in connection with the delivery of or payment for health care benefits, items, or services in a conspiracy with others; b) executing or attempting to execute this scheme or artifice to defraud with others; and, c) acting with intent to defraud. *U.S. v. Rogers*, 769 F.3d 372, 379-82 (6th Cir. 2014).

29. As described above, the Indictment fails to adequately plead that The defendants committed Health Care Fraud, therefore, whether he acted in concert with others or not, the defendants' alleged acts or failures to act cannot constitute Health Care Fraud Conspiracy.

30. Because the Indictment does not and cannot plead a cause of action against The defendants under 42 USC § 1349, Count 1 of the Indictment must be dismissed

under Rule 12(b)(1), Fed.R.Crim.P.

D. 42 USC § 1320a-7b(b)(1) and (2) (Illegal Remuneration Regarding Tricare)

i) The Illegal Remuneration Counts are Lesser Included Charges of Health Care Fraud if Alleged to Be Dishonest, so the Illegal Remuneration Counts Should be Dismissed.

31. Tricare Illegal Remuneration charges (42 USC §1320a-7b) constitute lesser-included charges of Health Care Fraud (42 USC § 1347) if dishonesty is alleged. *U.S. v. Ogba*, 526 F.3d 214, 232-35 (5th Cir. 2008) ("Thus, if Antoon's healthcare fraud conviction were based entirely on proof of his receipt of kickbacks, which he did dishonestly, then a conviction for illegal remuneration is a lesser included offense of healthcare fraud; building from the illegal remuneration conviction, the only additional element necessary for the health care fraud conviction is fraud or falsity.").

32. The Indictment expressly alleges in Sections 11 and 16 that the defendants utilized fraudulent and dishonest techniques in the alleged kickback scheme regarding the Tricare claims, making the Indictment's Illegal Remuneration claims lesser included charges of the Health Care Fraud counts. *U.S. v. Ogba*, 757 F.2d 1530, note 42 ("We find no language in the statutes or their legislative history suggesting an intent to allow conviction for illegal remuneration and health care fraud based on a charge of illegal remuneration arising from one act. If anything, the legislative history suggests that receipt of illegal remuneration is a subset of healthcare fraud, as it appears under the section entitled "Application of Certain Health Antifraud and Abuse Sanctions to Fraud and Abuse Against Federal Health Care Programs. P.L. 104-191, 1996 H.R. 3103 at 1999.").

33. Stated in the alternative, because the Indictment alleges dishonesty in the Illegal Remuneration counts, such allegations would constitute multiplicity in pleading and double jeopardy because the same is alleged in the Health Care Fraud counts. *U.S. v. Ogba*, 526 F.3d at 232-35; *U.S. v. Keys*, Case No. 17-10746, p. 9 (5th Cir. 2018) (Citing *Ogba* for the proposition that alleged offenses and lesser included offenses in the same indictment are mutiplicitous and constitute double jeopardy).

34. Therefore, the Illegal Remuneration allegations of the Indictment (42 USC §1320a-7(b)(1) and (2)), Counts 141 through 167, must be dismissed under Rule 12(b)(1), Fed.R.Crim.P.

ii) Even if the Illegal Remuneration Counts are Not Lesser Included Charges of Health Care Fraud, the Prescribing Physicians and Patients had "Freedom of Choice" of Pharmacies and Therefore The defendants Did Not Legally "Control" the Referrals.

35. The elements of Illegal Tricare Remuneration are: a) knowingly and willfully; b) receiving money, directly or indirectly; c) to induce the referral of individuals for medical goods or services; d) that are paid for by Tricare. *U.S. v. Vernon*, 723 F.3d at 252.

36. The defendants are alleged to have both accepted illegal Tricare remuneration (from several pharmacies) under 42 USC §1320a-7b(b)(1), and, paid illegal Tricare remuneration (to other sales representatives) under 42 USC §1320a-7b(b)(2).

37. There is limited criminal law on point, but civil false claims cases based upon violations of 42 USC § 1320a-7b(b) provide instructive authority (and if a kickback allegation fails to meet the civil law standards, certainly the heightened pleading and proof requirements of criminal law cannot be met). *U.S. ex rel.*

Greenfield v. Medco Health Solutions, Inc., 880 F.3d 89, 100 (3rd Cir. 2018) ("A kickback does not morph into a false claim unless a particular patient is exposed to an illegal recommendation or referral and a provider submits a claim for reimbursement pertaining to that patient. Even if we assume . . . illegal kickbacks, that is not enough to establish that the underlying medical care to any of the . . . patients was connected to a breach of the Anti-Kickback Statute; we must have some record evidence that shows a link between the alleged kickbacks and the medical care received . . . .").

38. It is particularly unusual for marketing agents such as the defendants, who lack: a) a professional healthcare license; b) a participating provider insurance contract; and c) the ability to bill a payer; to be in a position of sufficient control and authority to defraud a government health plan. *See U.S. v. Medina*, 485 F.3d 1291, 1297 (11th Cir. 2007) ("[I]n a health care fraud case, the defendant must be shown to have known that the claims submitted were, in fact, false.").

39. First, the falsity of the claim must be material in order to deem it fraudulent. *U.S. ex rel. Escobar v. Universal Health Services*, 136 S. Ct. 1989, 2002 (2017) ("A misrepresentation about compliance with a statutory, regulatory or contractual requirement must be material to the Government's payment decision in order to be actionable under the False Claims Act."); *Marsteller v. Tilton*, 880 F.3d 1302, 1312 (11th Cir. 2018) ("The materiality standard is 'demanding,' and 'rigorous.'"), *citing Universal Health Services v. U.S. ex rel. Escobar*, 136 S. Ct. at 2003.

40. This materiality standard is so demanding that even had the government payer actually known of the alleged kickbacks, that alone is legally insufficient. *U.S. ex rel. Escobar* v. *Universal Health Services*, 136 S. Ct. at 2003 ("A misrepresentation cannot be deemed material merely because the government designates compliance with a particular statutory, regulatory, or contractual requirement as a condition of payment. Nor is it sufficient for a finding of materiality that the Government would have the option to decline to pay if it knew of the defendant's noncompliance."); *U.S. ex rel. Petratos v. Genentech, Inc.*, 855 F.3d 481, 490 (3rd Cir. 2017).

41. In this case, subsequent to obtaining actual knowledge of potential non-compliance, the government waived remedial action, demonstrating a lack of materiality. *U.S. ex rel. Petratos v. Genentech, Inc.*, 855 F.3d at 490 ("Materiality may be found where 'the Government consistently refuses to pay claims in the mine run of cases based on noncompliance with the particular statutory, regulatory, or contractual requirement.' *Id*. On the other hand, it is 'very strong evidence' that a requirement is not material 'if the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated.'"), *citing U.S. ex rel. Escobar v. Universal Health Services, Inc.*, 136 S. Ct. at 2003.

42. In addition to establishing that a defendant had actual knowledge of the falsity of the government health plan claims, there must also be a showing of the defendant's knowledge of the materiality of such falsity. *U.S. ex rel. Escobar v.*

Universal Health Services, Inc., 136 S.Ct. at 1996 (Showing required that "the defendant knowingly violated a requirement that the defendant knows is material to the Government's payment decision."); *U.S. ex rel. Sikkenga v. Regency Bluecross Blueshield of Utah*, 472 F.3d 702, 714 (10th Cir. 2006) ("Generally, mere knowledge of the submission of claims and knowledge of the falsity of those claims is insufficient to establish liability under the FCA.").

43. Here, on 1/8/15, despite clear Committee findings of overutilization and potential program abuse, the Tricare Beneficiary Advisory Panel rejected a recommendation put forward by the Tricare Pharmacy and Therapeutics Committee to discontinue coverage of compounded medications, or impose a Prior Authorization requirement. *See TRICARE Votes to Continue Compounding*, *available at*: https://www.health.mil/About-MHS/OASDHA/Defense-Health-Agency/Operations/Pharmacy-Division/Beneficiary-Advisory-Panel/2015-Meeting-Archives.

44. Kickbacks can certainly generate fraudulent claims, but "remuneration cannot induce a referral unless it is directed towards a person with power [i.e., a physician] to make referrals." *Jones-McNamara v. Holzer Health Systems*, Case No. 15-3070, p. 15 (6th Cir. 2015) (Court ordered Motion for Summary Judgment for defendant regarding alleged kickbacks in false claims act case.); *U.S. ex rel. Perales v. St. Margaret's Hospital*, 243 F.Supp.2d 843, 852-54 (C.D. Ill. 2003) (The anti-kickback statute contemplates that the remuneration at issue be directed to an entity "in a position to generate Federal health care program business,"

meaning, a physician, and that "the person receiving the inducement is the one prohibited from making the referral to the entity that offered the remuneration.").

45. To show fraudulent claims due to kickbacks, the government must "provide legally sufficient evidence" the defendant "knowingly and willfully entered into an illegal kickback scheme." *Gonzalez v. Fresenius Medical Care of North America*, 689 F.3d 470, 476 (5th Cir. 2012) (District court granting defendant's Motion for Summary Judgment in false claims action because "[r]elator did not present any witness or document that would promote the inference of criminal intent to induce referrals."); *U.S. ex rel. Mastej v. Health Management Associates, Inc.*, Case No. 13-11859, p. 10; *U.S. v. Vernon*, 723 F.3d at 1252; *U.S. v. Starks*, 157 F.3d 833, 838-39 (11th Cir. 1998) (To violate the anti-kickback statute, a defendant must "act with knowledge that his conduct was unlawful.").

46. The legal standard at issue requires a showing that the defendant actually knew that the claims at issue were fraudulent. *U.S. v. Gonzalez,* 834 F.3d 1206, 1214 (11th Cir. 2016); ("[I]n a health care fraud case, the defendant must be shown to have known that the claims submitted were, in fact, false."), *citing U.S. v. Medina*, 485 F.3d 1291, 1297 (11th Cir. 2007).

47. A showing of an intent to commit a crime must be specific to the individual defendant, and a showing of bad intent through a series of events and a series of defendants, is entirely insufficient. *McGee v. Sentinel Offender Services, LLC*, 719 F.3d 1236, 1244-45 (11th Cir. 2013) (Court rejecting the concept of a group's "collective *mens rea*.").

48. In this case, the government can argue that "but for" the defendants' marketing activities, there might not have been the health insurance claims at issue, yet that is legally insufficient to show liability. *U.S. ex rel. Sikkenga v. Regence Bluecross Blueshield of Utah*, 472 F.3d 702, 714 (10th Cir. 2006) (Court rejected the "but for" causation test for false claims act liability).

49. The allegations in this case are that the defendants indirectly arranged for the referral of patients to pharmacies for medications in exchange for sales commissions from the pharmacies (because the direct referrals were necessarily the prescriptions from the patients' physicians).

50. Regardless, there is no allegation in this case that the defendants referred any patients to any pharmacies, and it was the pharmacies that paid sales commissions to the defendants.

51. The determination of whether any patients obtained a prescription, and which pharmacy would fill and dispense that prescription, was that of the patients' medical providers or the patients themselves.

52. Given that the prescribing physician and/or patient has the ultimate determination as to whether and/or where a script should be generated and filled, a marketer such as The defendants is not sufficiently in control of the circumstance to be legally responsible for the prescriptions. *See U.S. v. Miles*, 360 F.3d 480-81; *U.S. v. Iqbal*, Case No. 16-3065, p.10-11 (8th Cir. 2016).

53. Since a medical provider or patient always has the ultimate decision whether or where a script would be filled, marketers such as the defendants cannot as a matter of law be the "cause" of the prescription. *See U.S. v. Shoemaker*, 746 F.3d

614, 628 (5th Cir. 2014); *U.S. v. George*, 171 F. Supp.3d 810, 815 (N.D. Ill. 2016).

54. Only where a finder of fact determines that marketers such as the defendants are essentially in functional control of a patient referral stream and is being paid by a healthcare provider for such referrals (rather than being paid for marketing services), has the marketer violated the law. *See U.S. v. Vernon*, 723 F.3d at 1254-55; *see also U.S. v. Polin*, 194 F.3d 863, 864-65, 867, and *U.S. v. Starks*, 157 F.3d at 835-36.

55. If the patient referral stream is based upon physicians making the medical determination as to whether or not to prescribe, what to prescribe, and which pharmacy will dispense the medication, there is an "attenuation" that precludes the legal liability of a marketer. *U.S. v. Breathe Easy Pulmonary Services*, 597 F.Supp.2d 1280, 1292 (M.D. Fla. 2009), and *U.S. ex rel. Drescher v. Highmark*, 305 F.Supp.2d 451, 460 (E.D. Pa. 2004).

56. The allegation of a criminal kickback requires a showing of cause, and there is no showing that the defendants caused any prescriptions. *See U.S. ex rel. SNAPP v. Ford Motor Co.*, 532 F.3d 496, 505 (6th Cir. 2008).

57. Illegal remuneration can certainly be indirect, but regardless, it must be "directed towards a person with power to make referrals." *Jones-McNamara v. Holzer Health Systems*, Case No. 15-3070, p. 15; *U.S. ex rel. Perales v. St. Margaret's Hospital*, 243 F.Supp.2d at 852-54.

58. Tricare has been well-aware of, and issued specific guidance for, medical marketing arrangements for the promotion of healthcare goods or services for at least 20 years. *See* HHS-OIG Advisory Opinion 98-10 (providing for a 6-criterion test to determine whether commission-based sales of Medicare goods and services outside of a "safe harbor" would be found abusive or fraudulent), *available at*: https://oig.hhs.gov/fraud/docs/advisoryopinions/2019/AdvOpn19-02.pdf.

59. And, absent the government's showing of a lack of medical necessity for the prescriptions at issue, there is not even a loss to the government under the plain language of the Federal Sentencing Guidelines, §2B1.13(E)(I), in the event that kickback liability is found under 42 USC § 1320a-7b(b). *U.S. v. Medina*, 458 F.3d 1291, 1304 (11th Cir. 2007); *U.S. v. Guerra*, 307 Fed.Appx. 283, 285 (11th Cir. 2009).

60. In sum, because the Indictment does not, and cannot, allege the defendants stopped physician and patient "freedom of choice" of pharmacy, thereby effectively controlling the compounded medications' prescribing pattern, the Indictment does not plead a cause of action under 42 USC § 1320a-7b(b)(1) and (2) and therefore Counts 141 through 167 must be dismissed under Rule 12(b)(1), Fed.R.Crim.P.

E. 18 USC § 1341 (Mail Fraud)

61. The elements of Mail Fraud are: a) a scheme to defraud; b) which involves a use of the mails; c) for the purpose of executing the scheme. *U.S. v. Butcher*, 933

F.2d 1010, 1010 (6th Cir. 1991); *U.S. v. Henson*, 848 F. 2d 1374, 1378 (6th Cir. 1988); *U.S. v. Monica*, 787 F.2d 593, 593 (6th Cir. 1986).

62. In order to allege the crime of Mail Fraud, there must be a pleading that the defendant literally "caused" the fraudulent mailing. *U.S. v. Wuliger*, 981 F.2d 1497, 1504 (6th Cir. 1992).

63. "Cause" under 18 USC § 1341 can be pleaded in this case by showing that The defendants had a "reason to know" that the use of the mails to ship the medications to the patients somehow furthered the scheme to defraud. *U.S. v. Wuliger*, 981 F.2d at 1504.

64. The Indictment does not and cannot allege that the defendants had a "reason to know" that the mailing of medications or a money order furthered a scheme to defraud.

65. Such "reason to know" can be based upon an allegation of "fraudulent intent," but that is not to be found in the Indictment. *U.S. v. Campbell*, 845 F.2d 1374, 1383 (6th Cir. 1988).

66. Because there is no allegation in the Indictment that the Defendants had a "reason to know" that the Top Tier business model was a scheme to defraud the insurance plans by use of the mails, or that the defendants acted with "fraudulent intent," the Indictment fails to plead a cause of action for Mail Fraud and Counts 109 through 134 of the Indictment are subject to dismissal under Rule 12(b).

F. 18 USC § 1343 (Wire Fraud)

67. The elements of Wire Fraud are "nearly identical" to Mail Fraud: a) a scheme or artifice to defraud; b) the use of interstate wire communications in furtherance of

the scheme; and c) an intent to deprive a victim of money or property. *U.S. v. Martinez*, 588 F. 3d at 316; *see also U.S. v. Daniel*, 329 F.3d 480, 485 (6th Cir. 2003); *U.S. v. Prince*, 214 F.3d 740, 747-48 (6th Cir. 2000).

68. For the Indictment to adequately plead Wire Fraud, it must describe the "specific intent" of The defendants to defraud by means of being wired sales commissions from the pharmacies, and in turn wiring sales commissions to other marketers, and the Indictment fails to so plead. *U.S. v. Daniel*, 329 F.3d at 487; *U.S. v. Frost*, 125 F.3d 346, 371 (6th Cir. 1997) ("A defendant does not commit mail fraud unless he possesses the specific intent to deceive or defraud . . . .").

69. The Indictment fails to plead a cause of action for Wire Fraud and therefore Counts 2 through 108 are subject to dismissal under Rule 12(b).

G. 18 USC § 1957 (Money Laundering)

70. The elements of Money Laundering under 18 USC § 1957, are: a) the knowing engagement in a monetary transaction; b) of a value greater than $10,000; c) which involved criminally derived property; d) from specified unlawful activity; e) where the defendant knew that the transaction involved criminally derived property; and f) where the transaction took place within the United States. *U.S. v. Rayborn*, 491 F.3d 513, 517 (6th Cir. 2007).

71. As described in detail regarding Counts 109 through 134 and 2 through 108 above, as a matter of law, the defendants did not participate in a scheme to defraud and therefore were never engaged in any illegal activity and therefore did not violate 18 USC § 1957.

72. Because the Indictment fails to plead a cause of action for Money Laundering, Counts 172 through 178 are subject to dismissal under Rule 12(b).

III. LEGAL ANALYSIS

A. Commercial Insurance Health Care Fraud Allegations

73. The Health Care Fraud statute requires a showing of obtaining health care benefit program moneys "by means of false or fraudulent pretenses, representations or promises." *U.S. v. Davis*, 490 F.3d at 546.

74. "False or fraudulent pretenses" requires a showing of "some deception" to induce another to give up property or a legal right. *U.S. v. Raithatha*, 368 F.3d at 625; *U.S. v. Frost*, 125 F. 3d at 354; *U.S. v. DeSantis*, 134 F.3d at 764.

75. Because the Indictment fails to allege or show any fact, in any manner, how the defendants misrepresented anything or misled anyone in order to deceive, the Health Care Fraud counts fail as a matter of law.

B. Tricare Illegal Remuneration Allegations

76. It is well-established that if a legal standard (such as whether a Tricare claim for payment has been so materially tainted by a kickback as to make it "false" or "fraudulent" under the civil false claims laws) is subject to different reasonably objective interpretations, none of such reasonably objective legal interpretations will violate the civil false claims law. *See e.g., U.S. ex rel. Lamers v. City of Green Bay*, 168 F.3d 1013, 1018 (7th Cir. 1999) ("[D]ifferences in interpretation growing out of a disputed legal question are . . . not false" under federal law); *U.S. ex rel. Swafford v. Borgess Medical Center*, 98 F.Supp.2d 822, 828 (W.D.

Mich. 2000) (Technical violations of administrative regulations are not actionable under the federal law "unless the violator knowingly lies to the Government about them"), *aff'd*, 24 F.Appx. 491, 491 (6th Cir. 2001) ("[D]isputes as to the interpretation of regulations do not implicate False Claims Act liability"), *cert. denied*, 535 U.S. 1096, 122 S.Ct. 2292, 152 L.Ed2d 1051 (2002); *U.S. ex rel. Thompson v. Columbia/HCA*, 125 F.3d 899, 902 (5th Cir. 1997) ("[V]iolations of laws, rules, or regulations alone do not create a cause of action under the FCA"); *U.S. ex rel. Williams v. Renal Care Group, Inc*., 696 F.3d 518, 532 (6th Cir. 2012) ("The defendants are correct, irrespective of whether they in fact violated the regulations. The False Claims Act is not a vehicle to police technical compliance with complex federal regulations.").

77. To be actionable under the civil false claims laws, claims must be shown to be, objectively, an affirmative misrepresentation of any reasonable version of the truth (such as, whether the Tricare claims at issue were so materially tainted by kickbacks as to not be subject to payment). *Hindo v. University of Health Sciences/The Chicago Medical School*, 65 F.3d 608, 613 (7th Cir. 1995) ("In short, the claim must be a lie."), *cert. denied*, 516 U.S. 1114, 116 S. Ct. 915, 133 L.Ed.2d 846 (1996); *Wang v. FMC Corp.*, 975 F.2d 1412, 1416 (9th Cir. 1992); *Hagood v. Sonoma County Water Agency*, 81 F.3d 1465, 1478 (9th Cir. 1996).

78. The criterion of a knowing and willful act to violate the law (which is the standard under 42 USC § 1320-7b(b)) is so stringent that even if a defendant's actions were proven to be overreaching or excessive, if there is any ambiguity as to how a law

should be interpreted, liability will still not be found. *U.S. v. Southland Management Corporation*, 326 F.3d 669, 682 (5th Cir. 2003) ("[W]here disputed legal issues arise from vague provisions or regulations, a [government] contractor's decision to take advantage of a position can not result in his filing a 'knowingly' false claim."); *U.S. ex rel. Siewick v. Jamieson Science and Engineering, Inc*., 214 F. 3d 1372, 1378 (D.D.C. 2000); *Hagood v. Sonoma County Water Agency*, 81 F.3d at 1478-79.

79. In this case, even if the Tricare claims were objectively not subject to payment because they were materially tainted by kickbacks, the government would still have to demonstrate the defendants' bad knowledge and intent. *Commercial Contractors, Inc. v. U.S.*, 154 F.3d 1357, 1366 (D.D.C. 1998) ("If a contractor submits a claim based on a plausible but erroneous contract interpretation, the contractor will not be liable, absent some specific evidence of knowledge that the claim is false or of intent to deceive.").

80. This standard has been applied universally in federal courts, for many different substantive federal statutes other than the laws applicable to Tricare. *See e.g., U.S. v. Prigmore*, 243 F.3d 1, 13-14 (1st Cir. 2001) (Defendant in FDA fraud case entitled to objectively reasonable standard in evaluating allegedly false statements); *U.S. v. Rowe*, 144 F.3d 15, 21-23 (1st Cir. 1998) (Objective reasonable standard applied to alleged bankruptcy law fraud); *U.S. v. Migliaccio*, 34 F.3d 1517, 1525 (10th Cir. 1994) (Objective reasonable standard applied to

mail fraud allegations); *U.S. v. Bradstreet*, 135 F.3d 46, 52 (1st Cir. 1998) (Objective reasonable standard in securities fraud case).

81. The objectively reasonable standard is a determination of law, regardless of the facts, therefore, it may be utilized in a 12(b) Motion to Dismiss. *See e.g., Cheek v. U.S.*, 498 U.S. 192, 203, 111 S. Ct. 604, 112 L.Ed.2d 617 (1991).

82. While civil false claims obviously differ from criminal kickbacks, because the civil false claims laws expressly describe the minimum standards to show a kickback for false claims purposes, it is a distinction without a difference.

83. Again, while civil Tricare false claims law is not directly applicable to criminal Tricare kickback law, it is difficult to conceive of a circumstance where the government cannot plead a civil violation but can plead a criminal violation on identical facts.

84. In sum, the Illegal Remuneration counts in the Indictment are subject to a Motion to Dismiss because: a) there is no allegation or showing of fact that the defendants intentionally and knowingly marketed the compounded medications in exchange for arranging for Tricare patient referrals; b) there is no allegation or showing of fact that the defendants countered the "freedom of choice" of, thereby becoming effectively in control of, the Tricare patient referral stream; and c) there is no allegation that the Tricare claims at issue were objectively a misrepresentation to the government.

C. Scheme to Defraud Allegations (Pertaining to Wire Fraud, Mail Fraud, and Money Laundering)

85. A scheme to defraud is essentially a statutory derivation of the basic elements of common law fraud: "(1) an intentional misrepresentation of a material fact, (2) knowledge of the representation's falsity, . . . (3) an injury caused by reasonable reliance on the representation [and (4) the requirement] that the misrepresentation involve a past or existing fact. . . ." *Western Express, Inc. v. Brentwood Services, Inc.*, Case No. M2008-02227-COA-R3-CV, p. 10 (Tenn. App. 2009); *see also Dobbs v. Guenther*, 846 S.W.2d 270, 274 (Tenn. Ct. App. 1992).

86. "A claim of fraud is deficient if the complaint fails to state with particularity an intentional misrepresentation of a material fact." *Hermosa Holdings, Inc. v. Mid-Tennessee Bone & Joint Clinic, P.C.*, Case No. M2008-00597-COA-R3-CV, 2009 WL 711125, *10 (Tenn. Ct. App. 2009).

87. "To pass the particularity test, the actors should be identified and the substance of each allegation should be pled." *Hermosa Holdings, Inc. v. Mid-Tennessee Bone & Joint Clinic, P.C.*, Case No. M2008-00597-COA-R3-CV, 2009 WL 711125, *10; *Strategic Capital Reserves, Inc. v. Dylan Tire Industries, LLC,* 102 S.W.3d 603, 611 (Tenn. Ct. App. 2002).

88. The Indictment in this case fails to identify a single instance where the defendants made a misrepresentation of material fact to a health insurance plan or anyone else.

89. Because the Wire Fraud, Mail Fraud and Money Laundering counts of the Indictment fail to reasonably allege what the defendants did to break any law, they are so deficient as to be dismissed.

90. Essentially, the Scheme to Defraud-based allegations in the Indictment do not even allege what it is that the defendants did wrong, and therefore are subject to dismissal.

VI. SUMMARY

91. The Indictment in general fails to simply and clearly plead what the defendants did, or failed to do, that violated any law, which is a notice and due process deficiency. *U.S. v. Ball*, 12 F.3d at 214; *U.S. v. DeAndino*, 958 F.2d at 147-48; *Allen v. U.S.*, 867 F.2d at 971.

92. The government failed to properly plead violations of 42 USC § 1320a- 7b(b)(1) and (2) (Receipt and Payment of Illegal Remuneration);18 USC § 1347 (Health Care Fraud); 18 USC § 1349 (Conspiracy to Commit Health Care Fraud);18 USC § 1341 (Mail Fraud); 18 USC § 1343 (Wire Fraud); and, 18 USC § 1957 (Money Laundering). Because the Indictment fails to state a cause of action against the defendants, it is subject to dismissal pursuant to Rule 12(b), Fed.R.Crim.P.

Respectfully submitted,

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